

Appl. No.: 10/609,233  
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Amendments to the Claims:

1. (Original) An inhalable formulation for the treatment of pulmonary hypertension, said formulation comprising a therapeutically effective amount of a hypertension reducing agent, wherein said pulmonary hypertension reducing agent is at least one of an ACEI, ARB, beta-blocker, calcium-channel blocker or vasodilator and wherein said formulation is suitable for administration via inhalation to a mammal in need thereof.
2. (Original) The formulation of claim 1, wherein said formulation is suitable for administration via nebulization.
3. (Original) The formulation of claim 2 comprising about 0.001 mg/ml to about 20 mg/ml of said pulmonary hypertension reducing agent.
4. (Original) The formulation of claim 2 comprising about 0.1 mg/ml to about 15 mg/ml of said pulmonary hypertension reducing agent.
5. (Original) The formulation of claim 2 comprising about 1 mg/ml to about 10 mg/ml of said pulmonary hypertension reducing agent.
6. (Original) The formulation of claim 2, wherein said formulation is a solution.
7. (Original) The formulation of claim 6, wherein said solution is sterile.
8. (Original) The formulation of claim 7, wherein said solution is isotonic.
9. (Original) The formulation of claim 8, wherein said solution has a pH of about 3 to about 8.
10. (Original) The formulation of claim 9, wherein said solution comprises a buffer.
11. (Original) The formulation of claim 10, wherein said buffer is at least one selected from the group consisting of sodium hydroxide, sodium citrate and citric acid.

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12. (Original) The formulation of claim 2, wherein said formulation is an aqueous suspension.
13. (Original) The formulation of claim 12, wherein said suspension is sterile.
14. (Original) The formulation of claim 13, wherein said suspension comprises an emulsifier.
15. (Original) The formulation of claim 14, wherein said suspension is isotonic.
16. (Original) The formulation of claim 2, wherein said formulation comprises a preservative.
17. (Original) The formulation of claim 2, wherein said formulation is preservative-free.
18. (Original) The formulation of claim 2, wherein said ACEI is at least one of the group consisting of benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, perindopril, quinapril, ramipril andtrandolapril.
19. (Original) The formulation of claim 2, wherein said ARB is at least one of the group consisting of candesartan, eprosartan, irbesartan, losartan, olmesartan, telmisartan and valsartan.
20. (Original) The formulation of claim 2, wherein said beta-blocker is at least one of the group consisting of acebutolol, atenolol, betaxolol, bisoprolol, carteolol, carvedilol, esmolol, labetalol, metoprolol, nadolol, oxprenolol, penbutolol, pindolol, propranolol, sotalol and timolol.
21. (Original) The formulation of claim 2, wherein said calcium-channel blocker is at least one of the group consisting of amlodipine, bepridil, diltiazem, felodipine, flunarizine, isradipine, nicardipine, nifedipine, nimodipine and verapamil.
22. (Original) The formulation of claim 2, wherein said vasodilator is at least one of the group consisting of adenine, arginine, doxazosin, hydralazine hydrochloride, isosorbide

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dinitrate, isosorbide mononitrate minoxidil, nicotines, nitroglycerin, phentolamine, prazosin and terazosin.

23. (Original) The formulation of claim 2, wherein said vasodilator comprises one or more prostaglandins.

24. (Original) The formulation of claim 23, wherein said prostaglandin is prostacyclin or an analog thereof.

25. (Original) The formulation of claim 2, wherein said formulation is suitable for treating primary pulmonary hypertension.

26. (Original) The formulation of claim 2, wherein said formulation is suitable for treating secondary pulmonary hypertension.

27. (Original) A method of treating pulmonary hypertension in a mammal, said method comprising the step of administering to said mammal a formulation comprising a therapeutically effective amount of a hypertension reducing agent, wherein said hypertension reducing agent is at least one of an ACEI, ARB, beta-blocker, calcium-channel blocker or vasodilator, and wherein said formulation is suitable for administration via inhalation.

28. (Original) The method of claim 27, wherein said formulation is administered via nebulization to said mammal.

29. (Original) The method of claim 28, wherein said formulation is administered via jet nebulizer, ultrasonic nebulizer or breath-actuated nebulizer to said mammal.

30. (Original) The method of claim 27, wherein said formulation is premeasured, premixed and prepackaged.

31. (Original) The method of claim 30, wherein said formulation comprises about 0.05 mg/ml to about 15 mg/ml of said hypertension reducing agent.

32. (Original) The method of claim 31, wherein said formulation is sterile and stable.

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33. (Original) The method of claim 27, said method further comprising the step of administering to said mammal an anticoagulant.

34. (Original) The method of claim 27, said method further comprising the step of administering to said mammal an inotropic agent.

35. (Original) The method of claim 27, said method further comprising the step of administering to said mammal low-flow supplemental oxygen therapy.

36. (Original) The method of claim 27, said method further comprising the step of administering to said mammal a diuretic.

37. (Original) The method of claim 27, said method further comprising the step of administering to said mammal a low salt diet.

38. (Original) A kit for treating pulmonary hypertension in a mammal, said kit comprising an prepackaged formulation comprising a therapeutically effective amount of a hypertension reducing agent, wherein said hypertension reducing agent is at least one of an ACEI, ARB, beta-blocker, calcium-channel blocker or vasodilator, and wherein said formulation is suitable for administration via nebulization to a mammal in need thereof.

39. (Original) The kit of claim 38, wherein said formulation is prepackaged.

40. (Original) The kit of claim 38, further comprising instructions relating to said formulation.

41. (Original) An inhalable formulation for the treatment of pulmonary hypertension, said formulation comprising about 0.2-10.0 mg/ml, Enalaprilat, (s-1-[N-(1-carboxy-3-phenylpropyl)-L-alanyl]-L-proline dehydrate, about 2.0-10.0 mg/ml Sodium Chloride, Sodium Hydroxide and water, wherein said formulation is suitable for administration via nebulization to a mammal in need thereof.

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42. (Original) An inhalable formulation for the treatment of pulmonary hypertension, said formulation comprising about 1.0-10.0 mg/ml, Atenolol (Benzeneacetamide, 4-[2-hydroxy-3-(1-methylethyl)amino propoxy]), about 2.0-10.0 mg/ml Sodium Chloride, Sodium Citrate, Citric Acid and water, wherein said formulation is suitable for administration via nebulization to a mammal in need thereof.

43. (Original) An inhalable formulation for the treatment of pulmonary hypertension, said formulation comprising about 0.1-3.0 mg/ml Epoprostenol, about 0.2-2.0 mg/ml, Span 85 and water, wherein said formulation is suitable for administration via nebulization to a mammal in need thereof.

44. (Original) An inhalable formulation for the treatment of pulmonary hypertension, said formulation comprising about 0.1-10.0 mg/ml Treprostinil sodium, about 2.0-10.0 mg/ml, Sodium Chloride, Sodium Hydroxide, Citric Acid and water, wherein said formulation is suitable for administration via nebulization to a mammal in need thereof.

45. (Original) The formulation of claims 41 to 44, wherein said formulation is an aqueous suspension.

46. (Original) The formulation of claim 45, wherein said suspension is sterile.

47. (Original) The formulation of claim 46, wherein said suspension has pH of about 3 to about 8.

48. (Original) The formulation of claim 47, wherein said suspension is isotonic.

49. (Original) The formulation of claim 48, wherein said formulation comprises a preservative.

50. (Original) The formulation of claim 49, wherein said formulation is preservative-free.

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51. (New) An inhalable formulation for the treatment of pulmonary hypertension, said formulation comprising an aqueous suspension having a therapeutically effective amount of a calcium-channel blocker and wherein said formulation is suitable for administration via inhalation to a mammal in need thereof.

52. (New) The inhalable formulation according to claim 51, wherein said calcium-channel blocker includes at least one of the group consisting of amlodipine, bepridil, diltiazem, felodipine, flunarizine, isradipine, nicardipine, nifedipine, nimodipine and verapamil.

53. (New) The inhalable formulation according to claim 51, wherein the formulation comprises from about .001 to 10 mg/ml of said calcium-channel blocker and from about 0.01% to 90% of a suspending agent.

54. (New) The inhalable formulation according to claim 53, wherein said suspending agent comprises water, alcohol, glycol, aqueous saline solution, and combinations thereof.

55. (New) The inhalable formulation according to claim 52, comprising from about 0.01 mg/ml to 10 mg/ml of said calcium-channel blocker.

56. (New) The inhalable formulation according to claim 51, wherein said formulation is suitable for administration intranasally.

57. (New) The inhalable formulation according to claim 51, wherein said formulation is premeasured, premixed and prepackaged.

58. (New) The inhalable formulation according to claim 51, wherein said suspension includes at least one buffer selected from the group consisting of sodium hydroxide, sodium citrate and citric acid.

59. (New) The inhalable formulation according to claim 51, wherein said formulations is disposed in a dispensing container that is configured to deliver said formulation via nebulization.

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60. (New) The inhalable formulation according to claim 59, wherein said dispensing container is capable of delivering a single unit dose of a therapeutically effective amount of said calcium-channel blocker.

61. (New) The method of claim 27, wherein said calcium-channel blocker is at least one of the group consisting of amlodipine, bepridil, diltiazem, felodipine, flunarizine, isradipine, nicardipine, nifedipine, nimodipine and verapamil.

62. (New) The method of claim 27, wherein said formulation comprises from about 0.001 to 10 mg/ml of said calcium-channel blocker and from about 0.01% to 90% of a suspending agent.

63. (New) The method of claim 62, wherein said suspending agent comprises water, alcohol, glycol, aqueous saline solution, and combinations thereof.

64. (New) The method of claim 62, wherein said formulation comprises from about 0.01 mg/ml to 10 mg/ml of said calcium-channel blocker.

65. (New) The method of claim 27, further comprising the step of administering the formulation intranasally.

66. (New) The kit of claim 38, wherein said calcium-channel blocker is at least one of the group consisting of amlodipine, bepridil, diltiazem, felodipine, flunarizine, isradipine, nicardipine, nifedipine, nimodipine and verapamil.

67. (New) The kit of claim 38, wherein said formulation is prepackaged in a dispensing container that is configured to deliver a single unit dose of a therapeutically effective amount of said calcium-channel blocker via nebulization.

68. (New) The kit of claim 67, wherein said dispensing container is prefilled with about 0.1 to 5.0 ml of said formulation.

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69. (New) The kit of claim 67, wherein said formulation is administered via jet nebulizer, ultrasonic nebulizer or breath-actuated nebulizer to said mammal.



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